

**Notice of Allowability**

Application No.

10/656,838

Applicant(s)

CHENG ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to After final amendment, filed 4/23/07 and interview of 5/17/07.
2. ☒ The allowed claim(s) is/are 1-19, 34-38 and 40-46.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 5/17/07.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Leigh C. Maier  
Primary Examiner  
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## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1, 3 and 4 have been amended. Claims 21-26, 28-33 and 39 have been canceled. Claims 40-45 are newly added. Claims 1-19, 34-38 and 40-45 are pending. The examiner agrees with Applicant's characterization of the interviews leading to allowance.

The claims were interviewed once again on May 16, 2007. In updating the search in preparation for allowance, a newly issued US patent (Wang et al, US 7,141,540) was found. The reference discloses linear polymers having pendant cyclodextrins. The reference further suggests attachment of "targeting moieties." The reference describes targeting moieties as compounds that also have activity as therapeutic agents.

### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Carl Morales on May 16, 2007.

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IN THE CLAIMS:

*Claim 3, last line:* After “compound” insert -- and wherein at least one therapeutic agent or prodrug thereof is covalently attached to the polymer chain through attachments that are cleaved under biological conditions -- before the period (.).

*Add new claim:*

Claim 46. A method for delivering a therapeutic agent comprising administering to a patient in need thereof a therapeutically effective amount of one or more of the compounds of any of claims 1-4.

***Allowable Subject Matter***

Claims 1-19, 34-38 and 40-46 are allowed. The following is an examiner's statement of reasons for allowance: Wang et al (US 7,141,540) teaches linear polymers having pendant cyclodextrins. See, for example col 8, lines 25-65. These polymers may also have a targeting agent linked to the polymer. As discussed in Gonzalez et al (WO 00/01734 – of record), previously, the group of substances considered targeting agents overlaps with Applicant's definition of therapeutic agents. However, Wang provides no description or guidance that would suggest to one of ordinary skill a linker that would be cleaved under biological conditions. Yano et al (J. Pharm. Sci., 2001 – of record) teaches a conjugate comprising a cyclodextrin linked to a prednisolone via a succinate linker. The succinate linker qualifies as a monomer according to the definition in the specification. However, there is no teaching or suggestion to extend such a monomer into a polymeric compound. Moreover, the drug and the cyclodextrin are attached at the chemically active sites, thereby preventing any such extension.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Monday, Wednesday and Thursday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

*Leigh C. Maier*

Leigh C. Maier  
Primary Examiner  
May 17, 2007